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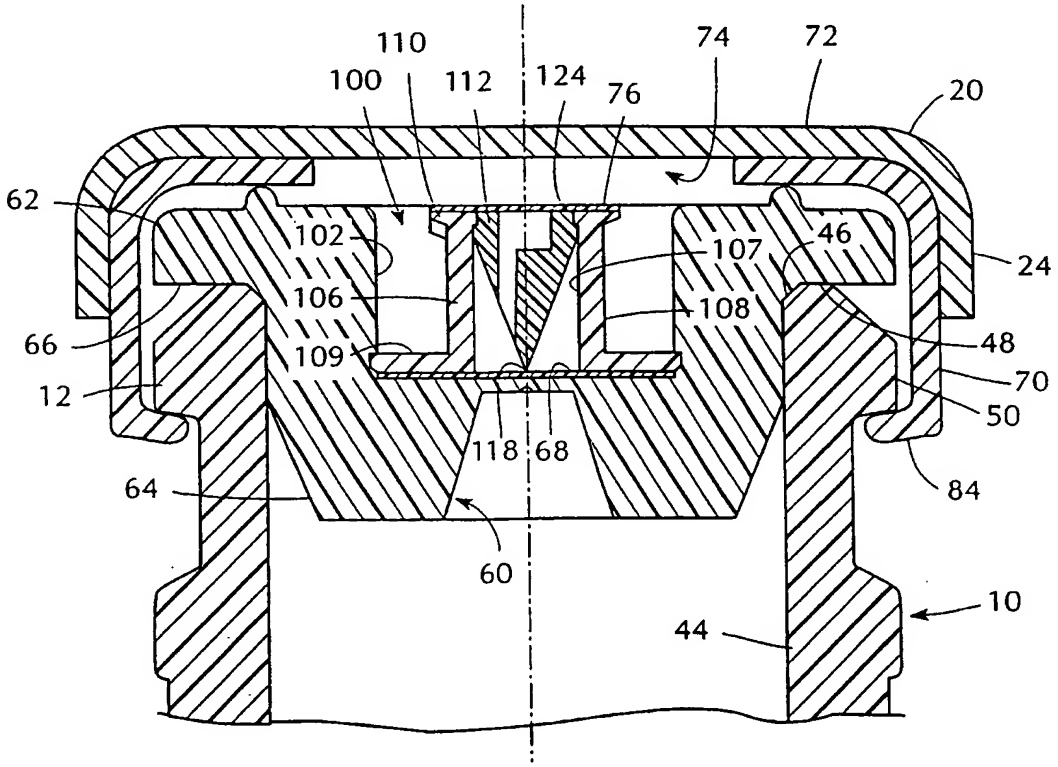
(54) Medicament container stopper with integral spike access means

(57) A closure assembly for containers and closure assembly/container combination for delivering medial fluid to a patient by needleless access means. The closure assembly comprises an elastomeric stopper (60) for sealing the container (10) at its open end and a spike access means equipped with a male luer connector (105).

FIG. 6



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Description

Field of the Invention

[0001] This invention relates to a closure assembly comprising a stopper having a spike access means used in conjunction with containers such as bottles, vials and bags containing pharmaceutical products for parenteral administration. More particularly, the invention relates to closure assembly comprising an elastomeric stopper for hermetically sealing a parenteral container, bottle, vial or bag the contents of which is accessed by the use of a spike integral with the stopper.

Background on the invention

[0002] The prior art has developed numerous devices to prevent accidental needle strike injuries to practitioners and patients. Such injuries are known to spread infectious diseases including hepatitis and AIDS. One of the main features of these devices is the lack of exposed sharp needles. The closures or stoppers have built in access means to the content of the containers, such as vials, cartridges, bags and bottles. The closures or stoppers in these devices serve the dual function of hermetically sealing the container while allowing access to the content therethrough.

[0003] Stoppers for containers such as vials and bottles are made of materials that are resistant to chemicals and pharmaceuticals such as corrosive materials, reagents, parenteral solutions and solid formulations reconstitutable with a solvent prior to use. The most commonly used stoppers for such products has been glass or plastic bottles and vials equipped with rubber stoppers made of elastomeric materials. The system provides for good hermetical seal, safe storage and easy access to the content through the elastomeric stopper via the use of an infusion needle or a syringe when withdrawal of the content is desired. The elastomeric stopper used generally comprises an elastomeric base, such as natural or synthetic rubber and an inert coating covering at least some portions of the stopper. The coating used includes chlorobutyl rubber, polymeric fluorocarbon resins such as polytetrafluoroethylene and various thermoplastic films. The coating is intended to insulate the elastomeric stopper base from the contents of the container in order to prevent contact and possible chemical reactions therebetween.

[0004] Generally, the elastomeric stopper is of cylindrical shape and has a flange head portion overlying the open top end of the container. Integral with the head portion is a body portion which extends into the open end and seated in the neck portion of the container, the diameter of the body portion being somewhat larger than the inside diameter of the container so that a tight seal is created between the body portion and the wall of the container. The lower end of the body portion is beveled towards the central, longitudinal axis of the body portion to facilitate the insertion of the body portion into the container. The circular bottom surface that faces the contents of the container is substantially planar and is imperforate, having no recess therein. The head portion of the stopper is provided with a central recess extending downwardly from the top thereof a substantial distance into the body portion so that the central recess and the circular bottom surface define a diaphragm. The walls forming the recess are generally cylindrical but may be provided with one or more circular protuberances extending inwardly to terminate just short of the center line of the stopper. The circular protuberances serve to press against and hold the needle of a syringe when the needle is inserted through the recess to penetrate the diaphragm for removal of the contents of the container. The elastomeric stopper is held in position by a metal ring or cap usually constructed of aluminum. The metal ring or cap has a removable center opening for allowing insertion of the syringe needle into the container.

[0005] Another type of the prior art stoppers has the needle penetrable diaphragm on the top portion of the stopper.

[0006] U.S. Patent Nos. 2,289,677 and 2,326,490 disclose a rubber stopper for use in vials comprising: an outer wall which serves as a seal between the vial and the stopper; and an inner wall forming a chamber in the center of the stopper, the bottom portion of the inner wall serving as a diaphragm. A hollow needle, having a sharp end for piercing the diaphragm, and an outer end exposed for connection with a syringe, is carried by the outer wall. A syringe connected to the outer end of the needle and pushed inwardly effects piercing of the diaphragm thereby permitting aspiration of the contents of the vial. After penetrating the inner wall, the syringe is detached and another hypodermic needle (presumably of smaller size) is used to withdrawn the contents and to inject the contents into a patient. In summary: a large bore needle is used first, then a fine bore needle is substituted for the large bore needle for the purpose of injection into the patient. Said patents require the use of sharp pointed needle, which still represent a serious inconvenience for practitioners and patients as above reported.

[0007] U.S. Patent No. 5,433,330 relates to a needleless access stopper used on containers. The stopper is used in conjunction with a cannula having a blunt penetrating tip. The stopper includes a disc and a plug extending from the disc into the container. Also included is a diaphragm defined by a target region in the upper face. Figures 28 and 29 show an embodiment intended for multi-dose usage. A cylindrical chamber 63 is axially centered within the stopper body 65 having a terminal end fitted with a truncated needle 67. A blunt cannula 23 is inserted through a pre-slit disc 59 and engages the needle body 65. When needle body is driven downward, the truncated end 67 punctures diaphragm

79. When the cannula is withdrawn, disc 59 re-seals the stopper to reduce or eliminate spray back. Said device, therefore, refers to a stopper for a multiple-dose usage, and does not allow a complete seal of the contents remained in the container after the cannula is withdrawn. Disc 59 is also required to prevent body 65 from coming out of the device (column 8, lines 47-48).

[0008] The stopper disclosed in U.S. Patent 5,433,330 shows a further number of drawbacks such as, for example, the fact that the blunt cannula 23 have to penetrate disc 59 before to join the needle 67 requiring a penetrating force to break it or the need of an overcap 17 provided with a piercing point 51. Then, the cannula 23 should be a cannula having a tip 25 which exactly fits into the tapered chamber 75. Further, once the cannula 23 has been pushed in order to penetrate the disc 59 and tip 25 has entered the tapered chamber 75, it is required an extra penetrating force in order to push downward the needle body 65 and allowing needle body ridge 69 to leave the engagement with extending groove 71 and engaging a second corresponding semi-circular circumferentially extending groove 73 of plug portion 27. Furtherly, once used, the sharp pointed needle comes out from the bottom of the plug portion 27 of the stopper and that can be seriously dangerous for technicians during the recycling process of the container.

[0009] None of the above cited prior art provides for a closure system assuring a complete seal of a container, containing a medical fluid, and at the same time being completely safe avoiding the use of sharp pointed needle.

Summary of the invention

[0010] The present invention relates to a new closure assembly providing sealing and needleless access means for containers and avoiding the use of a needle shaft inside said closure assenbly. The closure assembly according to the present invention is used with containers containing a medical fluid therein, and said closure having a needleless access means allowing withdrawal of the medical fluid from the container by the use of an intravenous tubing, a syringe or a mating luer connector attached to the needleless access means.

[0011] The closure assembly according to the present invention comprises:
an elastomeric stopper, for hermetically sealing a container at its open end, and a spike access means located in the upper center portion of said elastomeric stopper; said spike access means comprising:

(i) a spike;
(ii) a spike, located in said spike housing; and
(iii) a male luer connector, located in said spike housing.

[0012] Preferably, the closure assembly according to the invention comprises:
an elastomeric stopper, for hermetically sealing a container at its open end, and a spike access means located in the upper center portion of said elastomeric stopper; said spike access means comprising:

(i) a spike housing defined by a cylindrical side wall and comprising a horizontal stopper membrane forming the bottom of the spike housing;
(ii) a spike, having a male element on the upper end thereof and located in said spike housing; and
(iii) a male luer connector, located in said spike housing, and comprising a vertical cylindrical element;

said spike male element on the upper end of the spike and said vertical cylindrical element of male luer connector on the exterior of the spike housing being designed to twistably engage a female coupling to force and move the spike towards and penetrate the horizontal stopper membrane and thereby establish fluid communication with a medical fluid contained in said container.

[0013] According to another aspect, the closure assembly of the invention further comprises a cylindrical collar fastened over portions of the elastomeric stopper, and a removable cap which is removably attached to the top of the cylindrical collar.

[0014] According to a further aspect, the invention relates to a closure assembly/container combination, comprising the closure assembly according to the invention and a container.

[0015] The present invention provides sealing and needleless access means for containers, such as bottles or vials made of glass or plastic, and bottles and bags made of plastic containing medical fluids, such as x-ray contrast media and parenteral liquids. The needleless access means provides for hermetic sealing, safe handling, sterilization and storing. For convenience the invention will be described in combination with glass medicinal bottles. It is to be understood, however, that the invention includes sealing and access means for containers in general which comprise rigid or semi rigid access ports and are capable of receiving such sealing and access means

Brief description of the drawings

[0016] With reference to the annexed drawings, illustrating the invention:

FIG. 1A is a perspective view of a container, a stopper with spike access means, and a cap;
FIG. 1B is a perspective view of the top portion of the container, the stopper with spike access means shown in FIG. 1A without the cap;
FIG. 2 is a top plan view of the container and the cap;
FIG. 3 is a top plan view of the container, the stopper with spike access means shown in FIG. 1B;
FIG. 4 is a bottom plan view of the container;
FIG. 5 is a sectional view of the container, the stopper with the spike access means and the cap taken along the line 5-5 of FIG. 1A;
FIG. 6 is a sectional view of the neck portion of the container, the stopper with the spike access means and the cap taken along the line 5-5 of FIG. 1A;
FIG. 7 is a sectional view of the cap removed form the container shown in FIG. 1A;
FIG. 8 is an enlarged sectional view of the male spike housing and spike shown in FIG. 6;
FIG. 9 is a female connector which is to engage the male spike housing shown in FIG. 8; and
FIG. 10 shows the female connector shown in FIG. 9 engaging male spike housing shown in FIG. 9.

Detailed description of the invention

[0017] Referring to Figures 1A, 1B, 5 and 6, the container 10 having an open end in which the closure assembly of the present invention is used comprises a neck portion 12, a side portion 14, and a bottom portion 16. The closure assembly is covered with a cylindrical removable cap 18 having a flat top portion 20, a bottom portion 22 which is removably attached to the top cylindrical collar portion 70 of the container 10.

[0018] Referring to Figures 5, 6 and 8, the container 10 comprises a neck portion 12 having an interior surface 44, and interior radial end surface 46 on the top end portion of the interior surface 44, and transverse end surface 48. The interior radial surface 46 and the transverse end surface 48 form the mouth of container 10. The neck portion 12 further comprises an exterior surface which, adjacent to the transverse end surface 48, evolves into an exterior radial ring 50. The exterior radial ring is adapted to facilitate the holding of the closure assembly, described later.

[0019] The mouth of the container is to receive an elastomeric stopper 60, as shown in FIG. 6. The elastomeric stopper 60 comprises a head 62 and integral therewith a skirt 64. The head 62 comprises: a flange 66 extending laterally outwardly from skirt 64 and is adapted to cover transverse end surface 48 of container 10; stopper membrane 68; and sterility seal 69 which are designed to be pierced by the spike.

[0020] As best seen in FIG. 6 the container 10, after being filled with the desired amount of medical fluid, is sealed with the elastomeric stopper 60. To hold the elastomeric stopper securely in place, a cylindrical collar 70 is fastened over a portion of the elastomeric stopper 60 and the neck portion 12 of the container 10. The cylindrical collar 70 comprises:

- a flat top portion 72 having a central opening therein 74 which opening is optionally covered by an upper sterility seal 76; and
- an inwardly projecting ring 84 which securely holds stopper 60 in container 10.

[0021] Referring to FIGS. 6 and 8, spike housing generally designated as 100 is located in the upper center portion of stopper 60 and integral therewith, comprises:

- cylindrical wall 102; and
- stopper membrane 68 which forms the bottom, horizontal wall of the spike housing. Spaced from stopper membrane 68 and parallel therewith is optional lower sterility seal 69 which faces the content of container 10.

[0022] Within the spike housing 100 there is located a male luer connector 105 and a spike 112. The male luer connector 105 comprising:

- a vertical cylindrical element 106 having an outside surface 108, and an inside surface 107 facing spike 112;
- locking ears 110 on top portion of said vertical cylindrical element 106 to securely hold a female element;

the vertical cylindrical element 106 terminates in a horizontally oriented bottom portion 109 which extends into cylindrical wall 102 of spike housing 100 to firmly hold the luer connector in the elastomeric stopper 60.

[0023] The spike 112 comprising:

- a cylindrical shaft having a channel 116 therein, terminating in a sharp tip 118 at the lower end thereof; and
- a slideable plunger element 124 on the top portion thereof tightly facing inside surface 107 of vertical cylindrical element 106 of male luer connector to provide for a leak-proof seal when spike 112 is forced towards the content of the container; and
- a male element 114 on the upper end of the spike;

the spike male element 114 on the upper end of the spike and the vertical cylindrical element 106 of male luer connector on the exterior of the spike housing being designed to twistably engage a female coupling 140 to force and move the spike 112 towards and penetrate the horizontal stopper membrane 68 and thereby establish fluid communication with a medical fluid contained in the container 10.

[0024] The female luer connector is shown in FIG. 9 prior to its engagement with the male luer connector and in FIG. 10, when it engages the male element of the luer connector.

[0025] The female luer connector 140 shown in FIG. 9 comprises: cylindrical outside wall 142 and cylindrical inside wall 143 having an opening in their center portion for accommodating a tubing within the inside wall. Cylindrical ring 144 located in the top center portion of cylindrical inside wall 143 tightly holds tubing 160 which has a fluid communicating channel 162. Cylindrical inside wall 143 further comprises integral screw threads 146, 148, 150 and 152 which, upon connecting the female luer connector to the male luer connector, engages locking ears 110 on the male luer connector.

[0026] When it is desired to deliver medical fluid from container 10 to a patient, the cylindrical cap 18 is removed exposing the upper sterility seal 76 (optionally present), which is also removed manually. Upon removal of the upper sterility seal, the vertical cylindrical element 106 of the male luer connector is exposed to which female luer connector 140 is attached by twisting the female luer connector.

[0027] The female luer connector engages by its threads 146, 148, 150 and 152 the locking ears 110 on the male luer connector.

[0028] Upon turning the female luer connector 140, spike 112 is being forced to move toward the content of the container 10, first penetrating stopper membrane 68, followed by penetration of lower sterility 69 (optionally present) to establish fluid communication with the content of the container 10. As spike 112 travels downward into the container, slidable plunger 124 on spike 112 provides leak-proof contact between it and internal cylindrical wall 107 of male luer connector.

[0029] The medical fluid in the container is ready for delivery to the patients by turning the container upside-down.

Materials of Construction and Use

[0030] The elastomeric stopper used in conjunction with the spike access means of the present invention is fluid impervious, resilient, and inert without leachable additives therein in order to prevent any alteration of the product contained in the container. It may be of a single component or a blend of components. Examples of materials include synthetic and natural rubbers, such as butyl rubber, isoprene rubber, silicone rubber, halogenated rubber, ethylene propylene therpolymer and the like. Specific examples of a synthetic elastomeric rubber include the CH_2CF_2-C_3F_6 (C_3F_5H) and the C_2F_4-$C_2F_3OCF_3$ series of elastomers made by DuPont under the trade names of VITON® and CARLEZ®; the fluoro-silicone rubbers, such as those made by Dow Corning under the trade name of SILASTIC®; and polyisobutylenes, such as VISTANEX MML-100 and MML-140; and halogenated butyl rubber, such as CHLOROBUTYL 1066, made by Exxon Chemical Company.

[0031] These or other suitable elastomers may be made into the desired stopper configuration by known methods. Such methods conventionally include the use of a curing agent, a stabilizer and a filler and comprise a primary and a secondary curing step at elevated temperatures.

[0032] The container used in conjunction with the present invention may be of glass or a polymeric material, i.e., plastic, which are well known in the pharmaceutical industry. When the container is made of glass, it is in the shape of a vial or bottle.

[0033] Polymeric materials are preferred for reasons of economy and safety. The plastic containers may be in the shape of a vial, bottle or bag. The vial or bottle is of rigid or semi-flexible polymeric material, while the bag is of a pliable polymeric material. In all shapes the container is provided with a neck portion which is rigid and retains its configuration so that it is capable of being hermetically sealed by elastomeric stopper/spike access means of the present invention. The container may have a volume capacity of from 5 ml to 1000 ml or more, preferably about 10 ml to 500 ml.

[0034] The container may be of various configuration such as cylindrical, rectangular and oval and may be in the form of a bag, bottle or vial and may be constructed with rigid, semi-rigid or pliable walls. The mouth of the container, however, should be of cylindrical configuration and constructed form rigid or at least semi-rigid material.

[0035] The mouth of the container is to receive the elastomeric stopper. The external diameter of the stopper is slightly larger than the internal diameter of the neck of the container so that on insertion of the stopper into the mouth of the container, a tight, hermetic seal is achieved.

[0036] The cylindrical collar is preferably made of metal, such as aluminum, while the spike housing and spike are of hard plastic known by the prior art and used in conjunction with pharmaceutical fluids.

[0037] Prior to use, the container and component parts of the closure are sterilized and the container is filled with a pharmaceutical fluid, such as a parenteral solution.

[0038] The stopper containing the spike housing and spike with the luer connector thereon is inserted hermetically sealing the content of the container. Cylindrical collar is then crimped onto the container to securely hold the stopper in the container. Lastly, the cap is snapped onto the cylindrical collar to complete the closing of the container.

[0039] Upon requirement to withdraw the pharmaceutical fluid, the cap is removed by unsnapping it from the cylindrical collar and removing the upper sterility seal from the spike housing thereby exposing the male luer connector on the spike housing and male element on the spike. A female luer connector having an IV line attached thereto or being integral therewith is then made to engage the cylindrical element of the male luer connector and spike male element. The female luer connector is slowly screwed further into the male connectors thereby forcing the spike towards the stopper membrane and sterility seal which the sharp tip of the spike ruptures. Upon rupture, fluid communication is established between the content of the container and IV line attached to the female luer connector. To deliver the pharmaceutical fluid to the desired site, the container is turned upside down thereby allowing the pharmaceutical fluid to travel from the container to the site by gravity.

PARTS LIST	
Container	10
Neck portion of container	12
Side portion of container	14
Bottom portion of container	16
Cylindrical cap (of closure assembly)	18
Flat top portion of cap	20
Bottom rim portion of cap	22
Cylindrical side portion of cap	24
Interior surface of the neck portion of container	44
Interior radial end surface of the neck portion of container	46
Transverse end surface of container	48
Exterior radial ring of neck portion of container	50
Elastomeric stopper	60
Head of elastomeric stopper	62
Skirt of elastomeric stopper	64
Flange of head of elastomeric stopper	66
Stopper membrane	68
Lower sterility seal (Tyvec sterility seal)	69
Cylindrical collar	70
Flat top portion of cylindrical collar	72
Central opening in the flat top portion of the cylindrical collar	74
Upper sterility seal (Tyvec sterility seal)	76
Cylindrical side portion of cylindrical collar	78
Inwardly projecting ring	84
Spike housing	100
Cylindrical wall of spike housing	102
Male luer connector	105
Vertical cylindrical element of male luer connector	106
Inside cylindrical wall surface of male luer connector	107
Outside cylindrical wall surface on male luer connector	108
Bottom portion of male luer connector	109
Locking ears of male luer connector	110

(continued)

PARTS LIST	
Spike	112
Male element on the upper end of the spike	114
Channel within spike	116
Sharp tip of spike	118
Slidable plunger on spike	124
Female luer connector	140
Cylindrical outside wall of female luer connector	142
Cylindrical ring of female luer connector	144
Screw threads on inside all of female luer connector	146, 148, 150, 152
Tubing	160
Channel in tubing	162

[0040] The present invention has been described in connection with the preferred embodiment shown in the drawings, however, various changes and modifications will be apparent to those skilled in the art.

Claims

1. A closure assembly, providing sealing and needleless access for containers, comprising an elastomeric stopper (60), for hermetically sealing a container (10) at its open end, and a spike access means located in the upper center portion of said elastomeric stopper (60); said spike access means comprising:

   (i) a spike housing (100);
   (ii) a spike (112); and
   (iii) a male luer connector (105), located in said spike housing.

2. A closure assembly according to claim 1, wherein said spike access means comprising:

   (i) a spike housing (100) defined by a cylindrical side wall (102) and comprising a horizontal stopper membrane (68) forming the bottom of the spike housing (100), and optionally a removable sterility seal (76) on the horizontal top portion of the spike housing;
   (ii) a spike (112), having a male element (114) on the upper end thereof and located in said spike housing (100); and
   (iii) a male luer connector (105) located in said spike housing (100) and comprising a vertical cylindrical element (106);

   said spike male element (114) on the upper end of the spike and said vertical cylindrical element (106) of male luer connector on the exterior of the spike housing being designed to twistably engage a female coupling (140) to force and move the spike (112) towards and penetrate the horizontal stopper membrane (68) and thereby establish fluid communication with a medical fluid contained in said container (10).

3. A closure assembly according to claims 1-2, wherein said spike (112) (ii) further comprises:

   - a cylindrical shaft having a channel (116), terminating in a sharp tip (118) at the lower end thereof; and
   - a slideable plunger element (124) on the top portion thereof facing inside surface (107) of cylindrical element (106) of male luer connector (105) to provide a leak-proof seal when spike (112) is forced towards the content of the container.

4. A closure assembly according to claim 1, wherein said closure assembly further comprises:

   - a cylindrical collar (70) fastened over portions of the elastomeric stopper (60) and the container (10), said

cylindrical collar (70) having a central opening (74) in its flat top portion to allow access to a spike access means located in the elastomeric stopper (60); and

- a cap (18), wherein said cap (18) is covering the cylindrical collar (70) over the container (10).

5. A closure assembly/container combination, comprising the closure assembly of claims 1-4, and a container (10); wherein said container (10) contains a medical fluid therein.

6. A closure assembly/container combination according to claim 5, wherein said closure assembly having a needleless access means allowing withdrawal of said medical fluid from the container by the use of a tubing (160) attached to said needleless access means, said closure assembly/container combination comprising:

(a) a container (10);
(b) a closure assembly; and
(c) a cap (18),

wherein said container (10) containing a medical fluid therein, having a neck portion (12) terminating in an open end; wherein said closure assembly (b) inserted into the open end of said container (10), comprising:

- (1) an elastomeric stopper (60) for hermetically sealing the container (10) at its open end;
- (2) a cylindrical collar (70) fastened over portions of the elastomeric stopper (60) and the container (10), said cylindrical collar (70) having a central opening in its flat top portion to allow access to a spike access means located in the elastomeric stopper (60);
- (3) a spike access means, located in the upper center portion of said elastomeric stopper (60), comprising:
- (i) a spike housing (100) defined by a cylindrical side wall (102), a horizontal stopper membrane (68) forming the bottom of the spike housing (100), and optionally a removable sterility seal (76) on the horizontal top portion of the spike housing (100);
- (ii) a spike (112), having a male element (114) on the upper end thereof, and located in the spike housing (100); and
- (iii) a male luer connector (105) located in the spike housing (100) and comprising a vertical cylindrical element (106);

said spike male element (105) on the upper end of the spike and said vertical cylindrical element (106) of male luer connector (105) on the exterior of the spike housing being designed to twistably engage a female coupling (140) to force and move the spike (112) towards and penetrate the horizontal stopper membrane (68) and thereby establish fluid communication with the medical fluid contained in said container (10); and wherein said cap (18) is covering the cylindrical collar (70) over the container (10).

7. The closure assembly/container combination of claims 5 or 6, wherein said container (10) is made of glass.

8. The closure assembly/container combination of claim 7 wherein said container (10) is a vial.

9. The closure assembly/container combination of claim 7 wherein said container (10) is a bottle.

10. The closure assembly/container combination of claims 5 or 6 wherein said container (10) is a made of a polymeric material.

11. The closure assembly/container combination of claim 10 wherein said container (10) is a pouch or a bag.

12. The closure assembly/container combination of claims 5 or 6 wherein said medical fluid is a parenteral liquid.

13. The closure assembly/container combination of claim 12 wherein said parenteral liquid is an x-ray contrast medium.

14. The closure assembly/container combination of claim 12 wherein said parenteral liquid is a therapeutic liquid.

15. The closure assembly/container combination of claims 5 or 6 wherein the volume capacity of said container (10) is of from about 5 ml to about 1000 ml.

16. A closure assembly/container combination, said container (10) having a medical fluid therein, said closure assem-

bly having a needleless access means allowing withdrawal of said medical fluid from said container (10) by the use of a tubing (160) attached to said needleless access means, said closure/container combination comprising:

(a) a container (10);
(b) a closure assembly; and
(c) a removable cap (18) wherein said

(a) container (10) having a medical fluid therein, comprises:

a neck portion (12) having an interior radial end surface (46) and a transverse end surface (48) forming the mouth of said container (10);
an exterior surface which, with said transverse end surface (48), forms a radial ring (50) to receive and hold a cylindrical collar (70);

(b) a closure assembly inserted into the mouth of said container (10) comprising: (1) an elastomeric stopper (60); (2) a cylindrical collar (70); and (3) a spike access means, wherein said

(1) elastomeric stopper (60) comprises:

a head portion (62) and a skirt portion (64),
said head portion (62) having: a flange (66) extending laterally outwardly form said skirt portion (64) and is designed to cover the mouth of the container (10); and a recessed open central area designed to receive said spike access means; and
said skirt portion (64) projecting into the container (10) sealing the medical fluid contained therein;

(2) cylindrical collar (70) comprising:

a flat top portion (72) having a central opening therein (74) superimposed on the recessed open area in the head portion of the elastomeric stopper;
a cylindrical side portion (78) having an inner wall,
an outer wall, and
a bottom portion;
said inner wall having an inwardly projecting ring positioned below the exterior radial ring on the container to securely hold the elastomeric stopper (60) in the container (10);

(3) spike access means located in the upper center portion of said elastomeric stopper (60), comprises:

(i) a spike housing (100) defined by a cylindrical side wall (102), a horizontal stopper membrane (68) forming the bottom of the spike housing, optionally a horizontal sterility seal covering (69) the stopper membrane on the underside of the stopper membrane forming a barrier between the stopper membrane (68) and the medical fluid in the container (10), and optionally a removable sterility seal (76) on the horizontal top portion of the spike housing;
(ii) a spike (112) , located in said spike housing (100), comprises: a top portion, a side portion, and a bottom portion;

said top portion having a male element (114) thereon, a cylindrical shaft extending through the male element having a fluid communicating channel (116) therein and terminating in a sharp tip (118) at the other, bottom end thereof for piercing the membrane area (68) in said elastomeric stopper;
said side portion on the upper part thereof having a slidable plunger (124) pressing against internal cylindrical wall of a male luer connector; a male luer connector (105) located in the spike housing (110) and comprising:
a vertical cylindrical element (106) having an outside surface (108) and an inside surface (107) facing spike (112), and locking ears (110) on the top of said vertical cylindrical element (106);
said spike male element (114) on the upper end of the spike (112) and said vertical cylindrical element (106) of male luer connector (105) on the exterior of the spike housing (100) being designed to twistably engage a female coupling (140) to force and move the spike (112) towards

and penetrate the horizontal stopper membrane (68) and the optionally sterility seal (69) and thereby establish fluid communication with the medical fluid contained in said container (10); and

(c) removable cap (18), having a flat top portion (20), a bottom portion (22) which is removably attached to the top the cylindrical collar portion (70) of the container (10) in order to maintain the closure assembly free form contamination.

17. The closure assembly/container combination of claim 16 wherein said container (10) is made of glass.

18. The closure assembly/container combination of claim 17 wherein said container (10) is a vial.

19. The closure assembly/container combination of claim 16 wherein said container (10) is a bottle.

20. The closure assembly/container combination of claim 16 wherein said container (10) is made of a polymeric material.

21. The closure assembly/container combination of claim 20 wherein said container (10) is made of a flexible or pliable polymeric material.

22. The closure assembly/container combination of claim 16 wherein said container (10) is a pouch or bag.

23. The closure assembly/container combination of claim 16 wherein said medical fluid contained in said container (10) is an x-ray contrast medium.

24. The closure assembly/container combination of claim 16 wherein said medical fluid contained in said container (10) is a parenteral liquid.

25. The closure assembly/container combination of claim 16 wherein the volume capacity of said container is of from about 10 ml to about 500 ml.

FIG. 1B

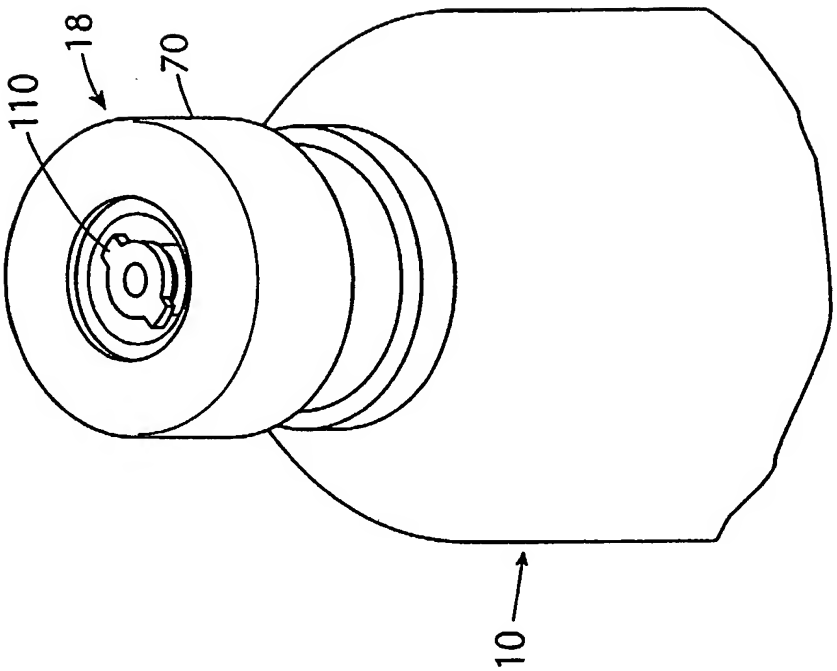

FIG. 1A

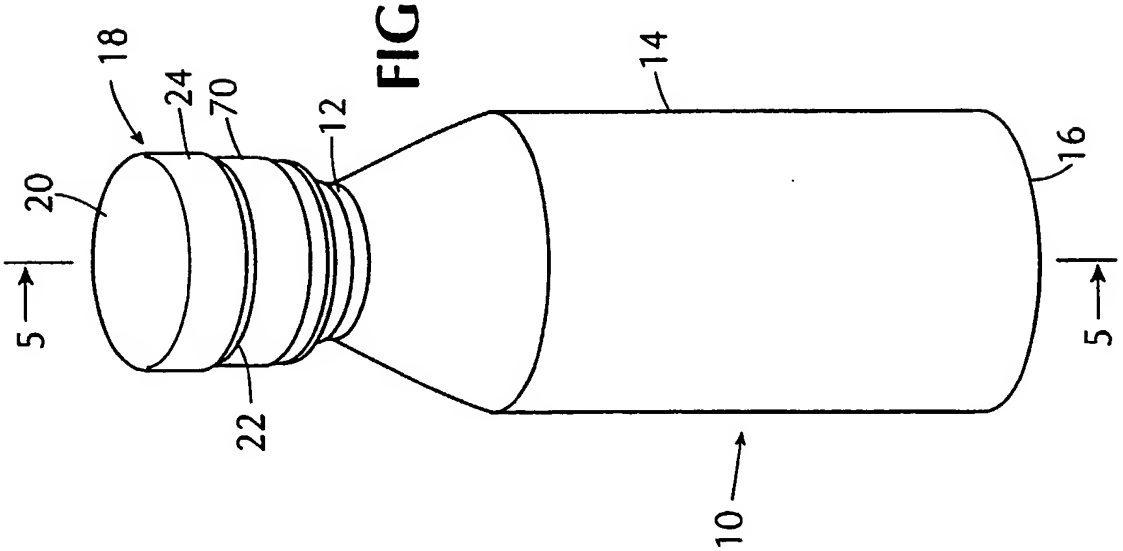

FIG. 2

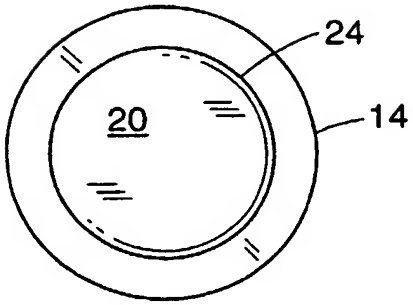

FIG. 4

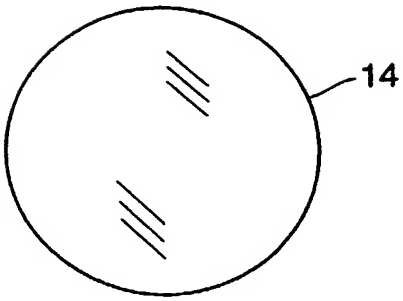

FIG. 3

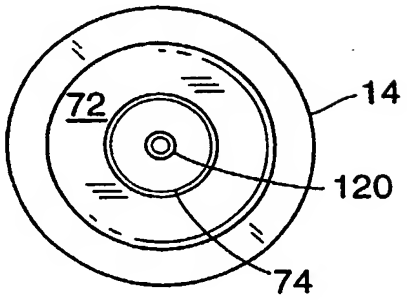

FIG. 7

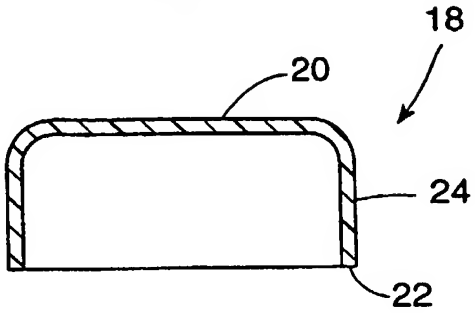

FIG. 5

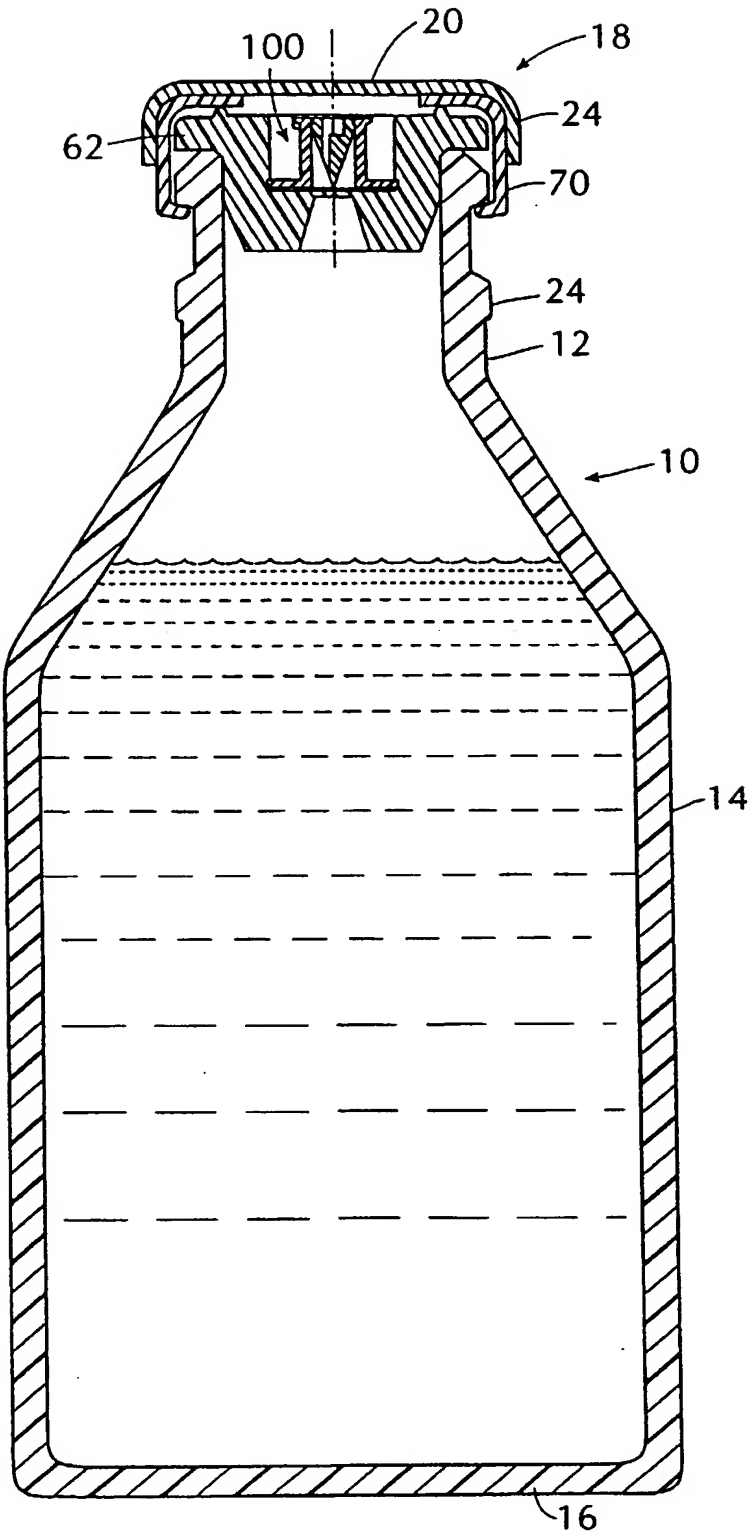

FIG. 6

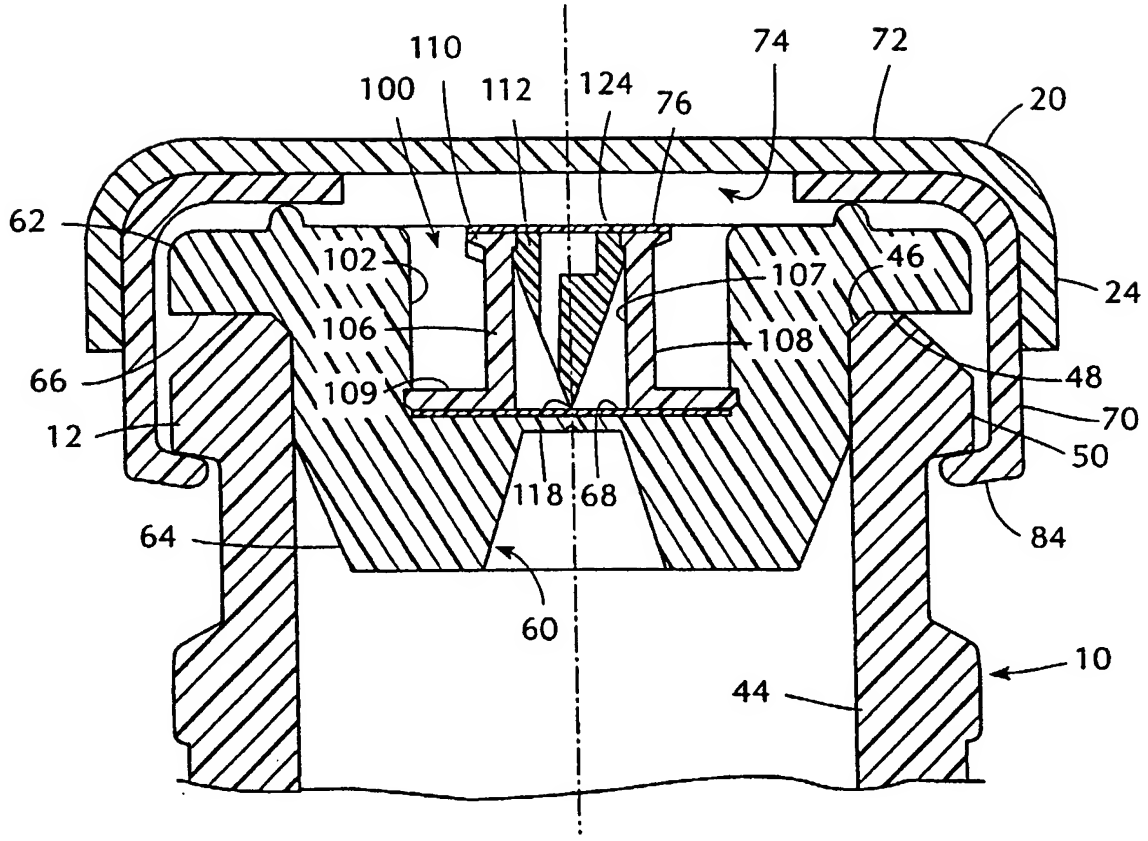
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FIG. 8

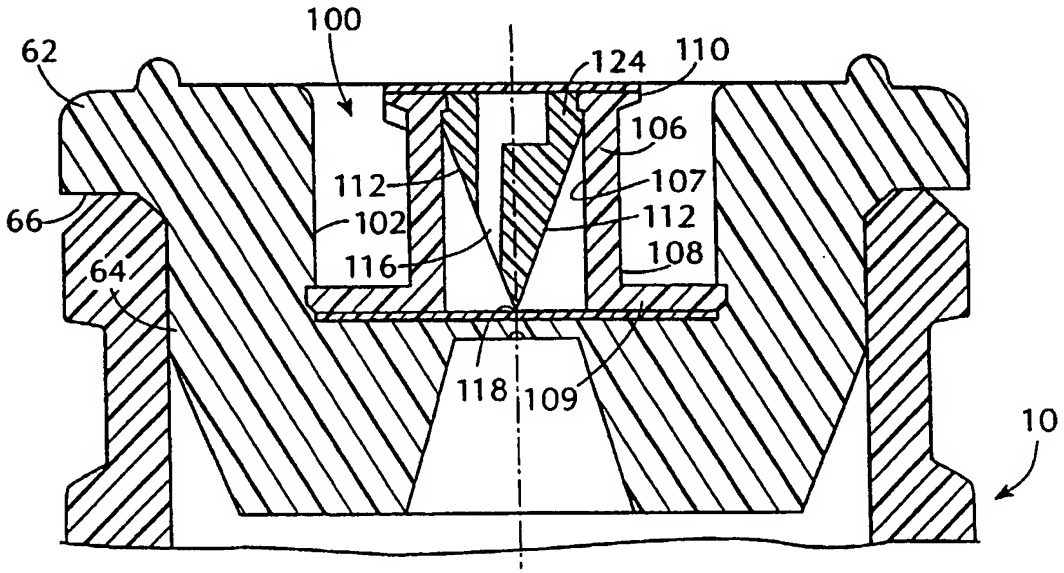
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FIG. 9

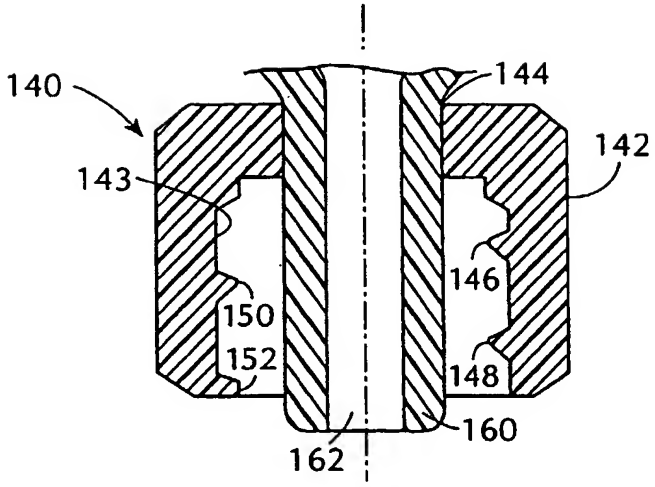
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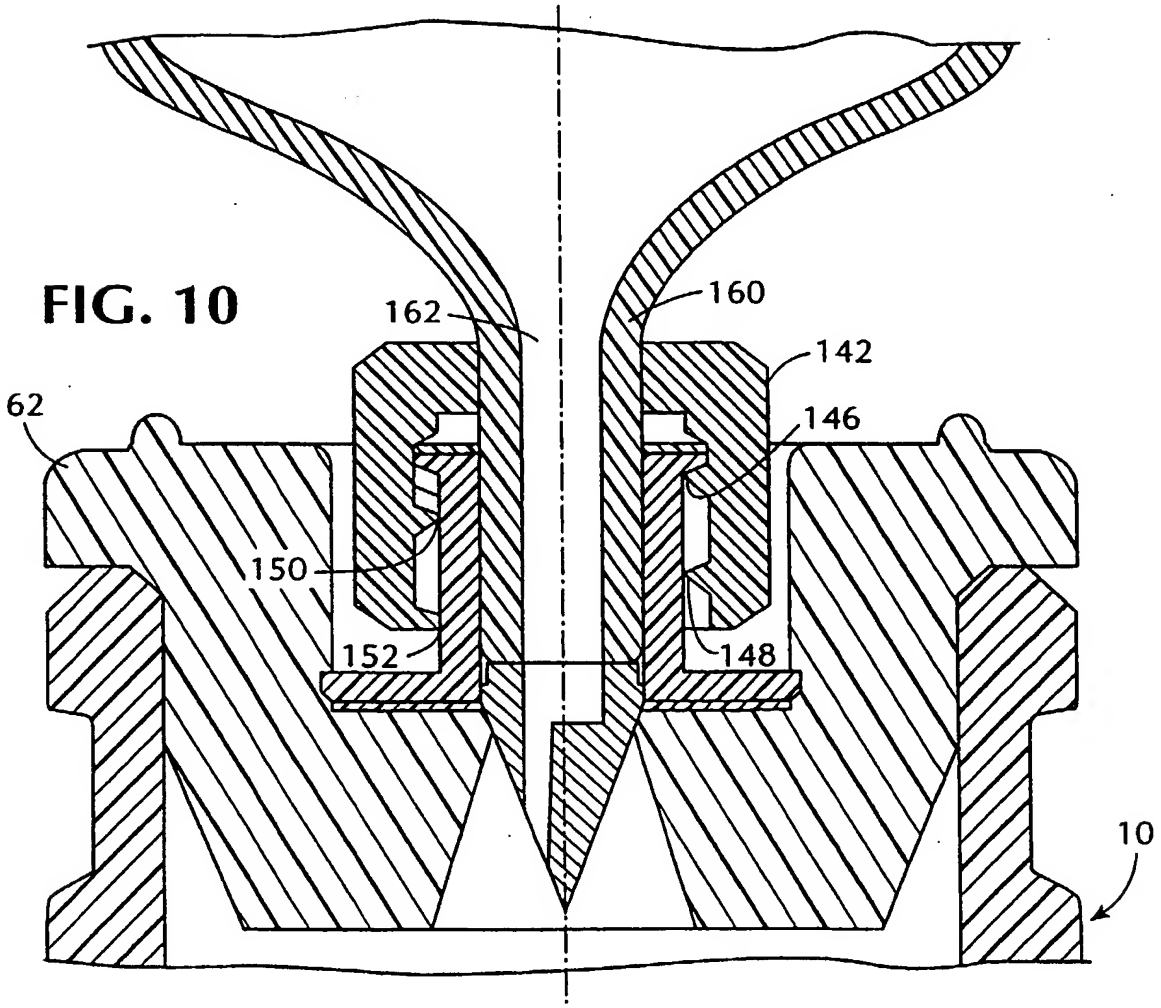
FIG. 10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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 10 3308

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A	WO 98 37855 A (ABBOTT LAB) 3 September 1998 (1998-09-03) * page 5, line 27 - page 6, line 1 * * page 10, line 4 - page 14, line 23 * * page 15, line 9 - line 11; figures 6-12 *	1,15,25	
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	20 July 1999	Baert, F

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